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EXAMINER
AFREMOVA, VERA

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1651	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/465,667	Applicant(s) Cedgart
	Examiner Vera Afremova	Art Unit 1651

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 23, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *11, 12, and 14-32* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *11, 12, and 14-32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

The request filed on 1/23/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/465,667 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 11, 12, 14-28 as amended and new claims 29-32 [Paper No. 15 filed 1/23/2002] are pending and under examination in the instant office action.

Claims 1-10 were canceled by applicant in Preliminary amendment [paper No. 8 filed 2/05/2001]. Claim 13 is canceled by applicant. [Paper No. 11 filed 5/21/2001].

Claim Rejections - 35 USC § 112

New matter

Claims 11, 12, 14-28 as amended and new claims 29-32 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1. Insertion of the limitation directed to a combination of two structural elements such as tablet friability range "between 0.1 and 1.0" and bacterial viability of "at least about 60 %" (see claims 11, 16, 22, 27 and 28) and insertion of the limitation directed to a combination of two structural elements such as tablet friability range "between 0.3 and 0.5" and bacterial viability of "at least about 60 %" (see new claims 29-32) have no support in the as-filed specification. The

insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of a combination of two structural elements as presently claimed.

There is only one exemplified disclosure (example 1, page 4) wherein the viability of lactic bacteria appears to be 60 % in the tablet with inulin or fructose oligosaccharide (for example: see page 4, line 33(100% bacterial viability minus 40% of reduction of CFU of bacteria = 60%) and the friability of the tablet of this example is 0.3 (page 4, line 30) but not the whole range as claimed. The only example 1 is not a sufficient support for the newly limited genus directed to a combination of the whole range for tablet friability such as "between 0.1 and 1.0" and the viability of bacteria such as "at least about 60 %" (see claims 11, 16, 22, 27 and 28). The only example 1 is not a sufficient support for the newly limited genus directed to a combination of the whole range for tablet friability such as "between 0.3 and 0.5" and the viability of bacteria such as "at least about 60 %" (see claims new claims 29-32). The presently claimed range for tablet friability "between 0.1 and 1.0" is said to be a conventional range for commercially acceptable products in the from of tablet (see specification page 3, lines 27-29) and the presently claimed range "between 0.3 and 0.5" is regarded by applicants as preferred friability of the tablets of the instant invention (page 3, lines 26). However, the example 1 demonstrates only one parameter of tablet friability which is 0.3. Thus, there is no sufficient support for the newly limited genera which encompass the use of whole ranges.

This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the limitation directed to a combination of two structural elements such as tablet friability range "between 0.1 and 1.0" and bacterial viability of "at least about 60 %" (see claims 11, 16, 22, 27 and 28) and the insertion of the limitation directed to a combination of two structural elements such as tablet friability range "between 0.3 and 0.5" and bacterial viability of "at least about 60 %" (see new claims 29-32) are considered to be the insertions of new matter for the above reasons.

✓ Canceled.

2. Insertion of the limitation directed to a particular composition (see claim 28, step a) wherein "the total amount bacteria provided is between 0.5-50% by weight with 40-99.5% by weight of inulin, 0-20% by weight microcrystalline cellulose, 0-20% by weight of calcium diphosphate and 0-15% by weight of starch" has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure of a composition with the presently claimed ranges of components, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of the composition as presently claimed. There is a generic disclosure drawn to a combination of live lactic bacteria and oligosaccharide (inulin) at concentration of 40-99.5% in one compressed product or tablet (page 2 lines 15-27) wherein the

generic is tablet is optionally comprises additives (page 3, lines 1-3). However, there is no neither generic no exemplified disclosure of any concentration ranges for additives. There are 2 particular examples of the final products (see pages 4 and 5) wherein inulin and other additives/binders which are claimed are present in two different compositions characterized by different viability of bacteria. This is not sufficient support for the newly limited composition as presently claimed.

This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the limitation directed to a particular composition (see claim 28, step a) wherein "the total amount bacteria provided is between 0.5-50% by weight with 40-99.5% by weight of inulin, 0-20% by weight microcrystalline cellulose, 0-20% by weight of calcium diphosphate and 0-15% by weight of starch" is considered to be the insertion of new matter for the above reasons.

Indefinite

Claims 11, 12, 14-28 as amended and new claims 29-32 rejected under 35 U.S.C. 112, ***second paragraph***, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 16, 22 and 27-32 are indefinite as related to the step b). It is uncertain what is "a force sufficient" (or hardness of the tablet) which is required to maintain bacterial viability at

the level of at least 60% as claimed. The claimed ranges of friability of the compressed product or tablet such as either 0.1-1.0 or 0.3-0.5 appear to be within the ranges which are commercially acceptable or commercially required for compressed products in the form of tablets (specification page 3, par. 4). Thus, it is unclear what is done or how the mixtures are compressed in order to obtained the final bacterial product with the viability as claimed and/or intended.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

as amended and new claims 29-32

Claims 11, 12 and 14-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable

J.A.

over US 5,531,989 [C] taken with US 4,806,368 [B-16], US 5,536,526 [A-16], US 5,422,346 [B], US 4,396,631 [A] and US 4,021, 545 [E].

The claims are directed to a method for producing tablets with live lactic bacteria comprising step of mixing live lactic bacteria with fructose oligosaccharide or inulin and step of pressing the mixture into tablet. The final tablet has a particular friability within 0.1-1.0. Some claims are/are further drawn to the use of particular species of lactic bacteria in the mixture such as *Lactobacillus bulgaricus, Lactobacillus plantarum, Streptococcus thermophilus or Bifidobacterium animalis*. Some claims are further drawn to the use of fructose oligosaccharide

or inulin at concentration 40-99.5% in the tablet. Some claims are further drawn to incorporation of additives into the tablet such as starch or calcium diphosphate.

US 5,531,989 [C] teaches a method for producing compositions with live lactic bacteria comprising step of mixing live lactic bacteria with fructose oligosaccharide or inulin and step of producing dry composition in the form of agglomerates wherein the final product comprises about 40-60 % by weight of inulin and/or fructose oligosaccharide and about 0.1-20% by weight of live lactic bacteria of *Lactobacillus sp.* and /or *Bifidobacterium sp.* including *L. bulgaricus* and *L. plantarum* (col. 13, lines 38-50 and col. 4, lines 1-30). The method of the cited patent clearly teaches the use of live lactic bacteria and inulin in the agglomerated product and the packaging of the product in a suitable container. But the cited patent is silent with regard to friability of the final product.

However, US 5,536,526 [A-16] is relied upon for the teaching of tableting techniques and for the disclosure related to criteria of tablet quality such as, for example: friability between 0% and 3% which is considered to be acceptable for most drug and food tablets (col. 4, lines 7-10).

The cited patent US 4,806,368 [B-16] teaches a method of making tablets with live lactic bacteria including bacteria belonging to genera of *Lactobacillus* and *Bifidobacterium* (abstract) and other additives such as dietary fibers, calcium phosphate (abstract or table at col. 3), cellulose (cl.1, line 26-28), etc. The cited patent clearly teaches that the viability of lactic bacteria and the extended shelf life of lactic bacteria during storage is considerably better for the bacterial compositions in the form of tablets than in the from of dry powder (col. 9, example 4) and the

viability appears to be more than 60% after 3 months of storage (table IV, col. 9). The cited patent also teaches that the tablets with live lactic bacteria were compressed to a hardness of 11-14 kg (col. 3, line 65). The cited patent teaches that use of dietary fibers such as apple fibers, for example, but it is lacking particular disclosure related to the use of the fructo oligosaccharide such as inulin in the tablets with live lactic bacteria.

However, the use of inulin is taught by US 5,531,989 [C] as explained above.

Moreover, US 5,422,346 [B] discloses the use of fructose oligosaccharide or inulin in the method for producing tablets and it teaches that inulin is compressed into tablets without the need of additional tableting material such as starch, for example : col. 8, lines 41-44. The cited patent also teaches that inulin is a growth promoting substrate of lactic bacteria such as *Bifidobacterium sp* and that pathogenic bacteria can not utilize inulin unlike beneficial bacteria in the gut of animals (col. 18, lines 25-37).

In addition, US 4,396,631 [A] teaches a method for method for producing tablets with live lactic bacteria by step of mixing live lactic bacteria with polysaccharide such as starch, for example, and/or other materials/additives suitable for tablets and step of pressing the mixture with a force sufficient to from tablets with viable bacteria. The cited patent clearly discloses that lactic bacteria retain high viability ($2x10^8$ cfu) after formation of compressed tablets as well as during storage of compressed tablets (col. 4, example 1). But the cited method is lacking the disclosure of fructose oligosaccharide or inulin in the mixture with live lactic bacteria intended for forming compressed products or tablets.

Further, US 4,021, 545 [E] teaches a method for producing tablets comprising both inulin and other additives such as starch or calcium diphosphate in one tablet (col. 5, example 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to provide dry products containing live or viable lactic bacteria and inulin which are characterized by commercially acceptable friability and/or hardness because hard tablets with live lactic bacteria are known in the prior art and they have been commercially available as adequately demonstrated by US 4,806, 368 [B-16] and by US 5,531,989 [C]. One ordinary of skill in the art would have been motivated to modify the form of packaging from powder to tablet because the viability of lactic bacteria during storage is considerably better for dry products in the form of tablets than in the form of powder as taught by the prior art {US 4,806, 368 [B-16]}. In addition, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute inulin for starch in the lactic bacteria containing tablets in the method of US 4,396,631 [A] with a reasonable expectation of success in obtaining pressed or compressed tablets since the use of inulin allows for the exclusion of additional tableting binders such as starch, for example, as taught by US 5,422,346 [B], thus, decreasing the cost of the tableting process. Accordingly, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments filed 1/23/2002 have been fully considered but they are moot in view of the new ground(s) of rejection.

Applicant' argument as related to a combination of the cited references A [US 4,396,631] and B [US 5,422,346], for example, that the present application demonstrates a superior viability of lactic bacteria tablets with inulin over the lactic bacteria tablets with starch (see response page 8, last par.) is not found persuasive because both tablets (either with inulin or with starch) as disclosed by applicant are characterized by the same friability of 0.3 which is within the presently claimed range between 0.1-1.0 or 0.3-0.5 and which is also within the commercially acceptable range for tablet friability 0-0.3 as taught by the prior art [US 5,536,526]. Therefore, the intended difference, if any, is uncertain as argued and as presently claimed.

The instant claim rejection under 35 U.S.C. 103(a) as being unpatentable over US 5,527,556 [D] has been withdrawn because the cited patent teaches the use of a cream/yogurt composition with live lactic bacteria and inulin rather than tablet with live lactic bacteria and inulin.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

Art Unit 1651

April 1, 2002.

Irene Marx

IRENE MARX
PRIMARY EXAMINER